510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
K040203

B. Analyte:
MDMA

C. Type of Test:
Qualitative visually read immunoassay

D. Applicant:
Branan Medical Corporation

E. Proprietary and Established Names:
Monitect MDMA Drug Screen Cassette Test
Fastect II MDMA Drug Screen Dipstick Test

F. Regulatory Information:

1. Regulation section:
   862.3100, Enzyme Immunoassay, Amphetamine
2. Classification:
   II
3. Product Code:
   DKZ
4. Panel:
   Toxicology (91)

G. Intended Use:

1. Intended use(s):
   Refer to Indications for use.

2. Indication(s) for use:
   The devices are a one-step, visually read, lateral flow, immunochromatographic immunoassay for the qualitative detection of 3,4-methylenedioxymethamphetamine (MDMA) in human urine at concentrations above 500 ng/ml. The Monitect® MDMA Drug Screen Cassette Test is an in vitro screening device and is intended for professional use only. The test is not intended for over-the-counter sale to non-professionals.

3. Special condition for use statement(s):

The devices provide only a preliminary analytical test result. A more specific alternative chemical method must be used to obtain a confirmed analytical result. Gas chromatography/Mass spectrometry is the preferred confirmatory method. Other chemical confirmation methods are available. Clinical consideration and professional judgment should be applied to any drug of abuse test result, particularly when preliminary positive results are used.

The assay is for Rx use.
The assay is not specifically designated for use in point-of-care settings, however the assay was evaluated in point-of-care settings.

4. Special instrument Requirements:
   Not applicable. The device is a visually read single-use device.

H. Device Description:

There are two formats of the same device described in this 510(k), a cassette and a dipstick device utilizing immunochromatographic technology. The products are unitized, for single-use. Operators either add 3 drops to the cassette or dip the test strip into the urine for 10 seconds to initiate the reaction. Results are visually read.

Only the method for applying sample to the test strip varies between the two products. There are also slight variations in the strip's dimensions. The read times both devices is 3-5 minutes. The cassette cannot be read beyond 15 minutes, while the dipstick version may be read for up to one hour. (The sponsor explains that the difference in maximum read times is because of the volume of sample added to the device.)

The sponsor has provided studies to support the read time recommendations and the equivalence between the two testing formats. Results show that between the minimum and maximum read times the results observed at plus and minus 25% of the cutoff concentration are the same. There is a variation in results between the minimum and maximum read times at the cutoff varies, e.g., at the minimum time there are 12 negative and 8 positive results, where as at the maximum time there are 15 negative and 5 positive results. I believe this is acceptable for this visually read technology. Additionally, the clinical impact is small because there are very few samples that are actually at the cutoff concentration of the assay.

I. Substantial Equivalence Information:

1. Predicate device name(s):
   SureStep Drug Screen MDMA One-Step Ecstasy Test (Applied Biotech)
2. Predicate K number(s):
   K011133
3. Comparison with predicate:
   Both devices are for the qualitative detection of the same analyte(s) in the same matrix, and utilize the same cutoff concentration. Both are visually-read single use devices. The manufacturers differ.

J. Standard/Guidance Document Referenced (if applicable):
The sponsor did not reference any standards in their submission.

K. Test Principle:
The tests employ lateral flow immunochromatographic technology.

The tests utilize a competitive immunoassay procedure where an immobilized drug conjugate competes with the drug present in urine for limited antibody binding sites. The test device contains a membrane strip, onto which the drug conjugate is coated at the test region. Colored antibody-colloidal gold conjugate is coated onto a pad and is placed at one end the membrane. In the test procedure, sample is added and allowed to migrate across the membrane by capillary action. If any drug is present in the urine sample, it competes with the drug conjugate for the limited binding sites on the colored antibody colloidal gold conjugate. When a sufficient amount of drug is present, the drug will saturate the antibodies, and the colored colloidal gold conjugate cannot bind to the drug conjugate on the membrane. The absence of a color band at the test region indicates a positive result. If there is no drug or drug metabolite present to compete for the binding sites of the colored colloidal gold conjugate, it binds to the immobilized drug conjugate to form a visible band at the test regions of the membrane. The presence of a color band at the test region indicates a negative result for the test. A control band with a different antigen/antibody reaction indicates that an adequate volume of sample was added and that the strip is intact.

Description of the test antibody: monoclonal mouse antibody against MDMA.

Description of the control line antibody: goat anti-rabbit antibody

L. Performance Characteristics (if/when applicable):

1. Analytical performance:
    a. Precision/Reproducibility:

    Specimen description: drug free urine spiked with MDMA
    Number of days: two
    Replicates per day: 10
    Lots of product used: three (one Monitect and 2 Fastect)
    Number of operators: three
    Operator: not specified
    Testing Facility: not specified.

    Pooled results from the study are presented below:

MDMA Precision Study Results, Pooled

Concentration of sample, ng/mL	Number of determinations	Results # Neg/ #Pos
250	60	60 / 0
375	60	177 / 3
500	60	**142 / 38**
625	60	21 / 159
750	60	1 / 179

Results between the dipstick and the cassette were similar.

A similar study was performed in POC locations by POC staff. The study, however, included only negative samples and those at plus 50% and minus 50% of the cutoff concentrations. At those concentrations the performance was equivalent to the in-house study data presented above.

It is interesting to note that the sensitivity, precision, and read time study results all show that the majority of samples at the cutoff concentration of the assay are negative. Results at 25% above the cutoff are acceptable, however, and the information appears in the labeling to alert users about performance at the cutoff.

b. Linearity/assay reportable range:
Not applicable. The assay is intended for qualitative use.

c. Traceability (controls, calibrators, or method):

There are no controls or calibrators provided with or specifically identified for use in the package insert.

The device has an internal process control. Users are instructed to follow federal, state, and local guidelines when determining when to run external controls.

d. Detection limit:

This information appears in the precision section, above.

e. Analytical specificity:
Cross-reactivity was established by spiking various concentrations of similarly structured drug compounds into drug-free urine. By analyzing various concentration of each compound the sponsor determined the concentration of the drug that produced a response

approximately equivalent to the cutoff concentration of the assay. Results of those studies appear in the table(s) below:

Reactivity of Assay

Drug Compound	Response equivalent to cutoff in ng/mL
d-amphetamine	Non-reactive at 100 µg/mL
l-amphetamine	Non-reactive at 100 µg/mL
d-methamphetamine	Non-reactive at 100 µg/mL
l-methamphetamine	Non-reactive at 100 µg/mL
3,4-Methylenedioxyethylamphetamine(MDEA)	250 ng/mL or 200%
D,L 3,4-Methylenedioxymethamphetamine (MDMA)	500 ng/mL or 100%
3,4-Methylenedioxyamphetamine (MDA)	2,000 ng/mL or 25%

There were many additional compounds evaluated by adding the compound into drug-free urine and observing whether the sample rendered a positive result. Compounds were tested at a concentration of 100 µg/mL. A complete listing of the compounds appears in the labeling. The following table lists the compounds which FDA recommends for testing of an amphetamine assay:

Compounds Tested for Specificity

Ranitidine (Zantac)	Not evaluated.
d- Pseudoephedrine	Non-reactive at 100 µg/mL
Ephedrine	Non-reactive at 100 µg/mL
Acetaminophen	Non-reactive at 100 µg/mL
Acetylsalicyclic Acid	Non-reactive at 100 µg/mL
Ibuprofen	Non-reactive at 100 µg/mL
Ascorbic acid	Non-reactive at 100 µg/mL
Albumin	Non-reactive at 100 µg/mL

To test for potential interference from pH and specific gravity the sponsor prepared a study control sample. The control sample consisted of drug-free urine spiked with MDMA at 500 ng/mL. The pH and specific gravity of the samples was varied across a range of conditions. Results from the altered samples were compared to results from the unaltered sample. There was no variation in test results across the following range:

4.5-8.5 pH
1.005 to 1.030 specific gravity

f. Assay cut-off:

Characterization of how the device performs analytically around the claimed cutoff concentration appears in the precision section, above.

2. Comparison studies:

   a. *Method comparison with predicate device:*
   The accuracy of the Monitect® MDMA Drug Screen Cassette Test was evaluated by comparison to the predicate, the SureStep MDMA One-Step Ecstasy Test and to GC/MS. Forty urine samples were collected from presumed drug-free Branan employees and tested by both the Monitect® and SureStep™. Of the 40 samples tested, all were found negative by both methods (100% agreement). Additionally, forty clinical urine specimens with known MDMA concentrations (previously analyzed by GC/MS) were tested by both the Monitect® and SureStep™. The two products obtained the same results on all 80 samples.

   Sample description: All 40 negative and 32 of the positive samples were unaltered clinical urine samples. Eight additional positive samples consisted of diluted samples. These were included in the study so as to evaluate samples near the cutoff concentration of the assay. They were prepared by diluting clinical samples with high drug concentrations with drug-free urine.

   Sample selection: Sample selection criterion was not described by the sponsor. Samples were obtained from a laboratory.

   Number of study sites: not specified

   Type of study site(s): not specified

   Operator description: not specified.

Candidate Device Results vs. stratified GC/MS Values

Candidate Device Results	**Negative** by GC/MS analysis	**Near Cutoff Negative** (Samples diluted to 375 ng/mL MDMA)	**Near Cutoff Positive** (Samples diluted to 625 ng/mL MDMA)	**High Positive** (greater than 625 ng/mL)
Positive	0	0	4	32
Negative	40	4	0	0

GC/MS values used to categorize samples in this table are MDMA results, alone. Results from the dipstick format were essentially the same.

Point of Care Study: To assess the Accuracy of Monitect® MDMA Drug Screen Cassette Test, the same samples were evaluated in three POC locations by POC staff. Essentially the same results were observed.

b. Matrix comparison:
Not applicable. The assay is intended for only one sample matrix.

3. Clinical studies:
   a. Clinical sensitivity:
   Not applicable. Clinical studies are not typically submitted for this device type.
   b. Clinical specificity:
   Not applicable. Clinical studies are not typically submitted for this device type.
   c. Other clinical supportive data (when a and b are not applicable):

4. Clinical cut-off:
   Not applicable.

5. Expected values/Reference range:
   Not applicable.

M. Conclusion:

I recommend that this device be found substantially equivalent to the predicate device.